

### REMARKS

Favorable reconsideration of the subject patent application is respectfully requested in view of the above amendments and the following remarks. Following the amendments, claims 6-9, 26, 27, 29, 34 and 36-39 are under consideration.

Applicants wish to thank the Examiner for his helpful telephone discussions with the applicants' representative on August 16 and September 1.

A substitute sequence listing was submitted electronically for the subject patent application on February 17, 2004, however it is the applicants' understanding that the substitute sequence listing was not entered. Accordingly, the substitute sequence listing is resubmitted herewith. The sequence listing has been amended to correct obvious errors. More specifically, the DNA sequence SEQ ID NO: 13 has been correctly renumbered as SEQ ID NO: 25, and polypeptide sequences SEQ ID NO: 14-25 have been correctly renumbered as SEQ ID NO: 13-24, respectively. The DNA sequences SEQ ID NO: 1, 3, 5, 7, 8, 10 and 12, and the corresponding polypeptide sequences SEQ ID NO: 13, 15, 17, 19, 20, 22 and 24, have been corrected to show that the sequences were isolated from *Lolium perenne*, rather than *Festuca arundinacea*. It is urged that support for these amendments may be found in Table 1 (pages 14-16) and Example 1 (page 38, line 1 - page 39, line 10) of the specification as originally filed, and also in originally filed Figs. 1-13, and that these amendments do not constitute new matter. The substitute sequence listing is consistent with the originally filed disclosure and Figures.

Applicants hereby affirm that, following entry of the substitute sequence listing, they wish to elect the polypeptide sequence of SEQ ID NO: 15. Applicants reserve the right to rejoin method claims 25, 28 and 35 with the elected product claims once the product claims are found to be allowable.

Claims 10-17 and 20-23 have been cancelled as being drawn to non-elected inventions. Claim 9 has been amended to remove reference to sequences having at least 75% identity to SEQ ID NO: 15 and to functional portions of SEQ ID NO: 15. Claims 25, 26, 28, 29, 31 and 34 have been amended to remove reference to claim 9. Newly added claims 37-39 are drawn to subject matter previously recited in claims 26, 27, 29 and 34 respectively.

It is urged that support for all the above amendments may be found throughout the specification as originally filed and that none of the amendments constitute new matter. It is

further submitted that the amendments are not being made for reasons of patentability and therefore do not give rise to prosecution history estoppel.

***Claim Rejections under 35 U.S.C. §112, first paragraph - written description***

Claims 9, 26, 27, 29 and 34 stand rejected under 35 USC §112, first paragraph, as lacking an adequate written description. Specifically, the Examiner has objected to the recitation of polypeptides comprising a sequence having at least 75%, 90%, 95% or 98% identity to the specifically recited SEQ ID NO: or a functional portion of the specifically recited SEQ ID NO:, wherein the polypeptide possesses an ability to bind ice crystals.

As noted above, claims 26, 27, 29 and 34 have been amended to depend from allowable claims 6-8, and thus the rejection of these claims is moot. Following the amendments, claim 9 is drawn to polypeptides comprising a sequence at least 90%, 95% or 98% identity to SEQ ID NO: 15, and that have an ability to bind ice crystals.

The Examiner asserts that “the variants (as claimed) have been defined only by a statement of function that broadly encompasses an ability to bind ice crystals-like activity, which conveyed no distinguishing information about the identity of the claimed amino acid sequence, such as its relevant structural or physical characteristics”. Applicants respectfully disagree. The variant sequences recited in claim 9 have **not** been defined **only** by a statement of function. Rather the recited sequences have been defined by **both** a statement of function **and** a clearly stated structural relationship to SEQ ID NO: 15, namely either 95%, 90% or 98% identity to SEQ ID NO: 15. As stated on page 8, lines 12-19, of the specification as originally filed, Fig. 3 of the application clearly presents conserved motifs that have been previously identified in antifreeze proteins. Claim 9 does not encompass polypeptides having sequence variations in these motifs, as asserted by the Examiner, that would render the polypeptide unable to bind to ice crystals, as the claim clearly requires that the polypeptides possess this functional activity.

Furthermore, applicants note that, in the Responses to Specific Comments on the Guidelines for Examination of Patent Applications under 35 USC §112, first paragraph, “Written Description Requirement” (Federal Register Vol. 66, No. 4, January 5, 2001), it is clearly stated that “[d]escribing the complete chemical structure, i.e., the DNA sequence of a claimed DNA is one method of satisfying the written description requirement but it is not the only method”. The

Response further states “[t]here is no basis for a per se rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed”. Applicants also note that the Guidelines themselves state “The written description requirement for a claimed genus may be satisfied ... by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics”. The Guidelines further state that “[d]isclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient”.

It is urged that the presently claimed polypeptides possess sufficient common identifying characteristics, namely specific percentages of sequence identity and clearly recited functional characteristics, to clearly distinguish the claimed polypeptides from other materials and that these identifying characteristics would indeed lead one of skill in the art to conclude that the applicant was in possession of the claimed invention at the time the application was filed.

Applicants respectfully submit that claims 9, 26, 27, 29 and 34 fully satisfy the written description provision of 35 USC §112, first paragraph, and that this rejection of the pending claims may thus be properly withdrawn.

***Claim Rejections under 35 U.S.C. §112, first paragraph - enablement***

Claims 9, 26, 27, 29 and 34 stand rejected under 35 USC §112, first paragraph, as lacking an enabling disclosure. Specifically, the Examiner states that the specification “does not reasonably provide enablement for any and all natural or non natural variants of SEQ ID NO: 15”. This rejection is respectfully traversed.

The Examiner asserts that “the invention as claimed encompasses variation in conserved amino acid sequence domain that is considered essential for an ability to bind ice crystals”; that “applicant wish to identify a variant that does not even comprises the conserved amino acid sequences required for antifreeze activity” and the “variants as claimed are only hypothetical proteins because no biological function has been established”. Applicants respectfully disagree.

Claim 9, as amended, is drawn to polypeptides comprising a sequence having at least 90%, 95% or 98% identity to SEQ ID NO: 15, **wherein the polypeptide possesses an ability to bind ice crystals**. As discussed above, regions of SEQ ID NO: 15 showing homology to conserved motifs previously shown to be present in anti-freeze proteins are shown in Fig. 3 of the instant specification. If a polypeptide comprising a variant sequence of SEQ ID NO: 15 contains sequence modifications in these regions that affect the functional activity of the polypeptide, then the polypeptide will not possess an ability to bind ice crystals and will therefore not fall within the scope of claim 9. Accordingly, it is urged that claim 9 does **not** encompass either sequences having variations in domains considered essential for an ability to bind ice crystals or variants that do not comprise the conserved amino acid sequences required for activity.

Methods for identifying polypeptides comprising a sequence having at least 90%, 95% or 98% identity to SEQ ID NO: 15 are clearly described in the specification at page 23, line 10, page 25, line 27. Assays for determining whether such variants are able to bind ice crystals are well known to those of skill in the art. Applicant notes that, as stated in §2164.01(a) of the Manual of Patent Examining Procedure (MPEP), the level of predictability in the art is only one of many factors to be considered when determining whether or not a disclosure satisfies the enablement requirement and that other factors to be considered include, but are not limited to, “the level of one of ordinary skill in the art” and “the amount of direction provided by the inventor”. It is noted that the level of skill in the field of biotechnology is generally be accepted to be quite high. §2164.01 of the MPEP also states “[t]he fact that experimentation may be complex does not necessarily make it undue if the art typically engages in such experimentation”.

Applicants thus respectfully submit that claims 9, 26, 27, 29 and 34 fully satisfy the enablement requirements of 35 USC §112, first paragraph, and that the rejection of these claims under 35 USC §112, first paragraph, may be properly withdrawn.

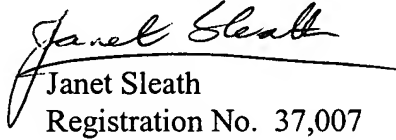
### ***Concluding Remarks***

A Request for a One Month Extension of Time extending the deadline for responding to the Office Action to September 17, 2005, is submitted herewith. The subject application recently became eligible for small entity status, therefore the small entity fee is submitted herewith.

Applicants note that the Examiner has indicated that claims 6-8 are allowable. Early reconsideration and allowance of all the pending claims is respectfully requested.

Should the Examiner have any further concerns regarding the subject patent application, he is respectfully requested to telephone the undersigned at 206.382.1191.

Respectfully submitted,

  
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